

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY )	
AVERAGE WHOLESALE PRICE )	MDL No. 1456
LITIGATION )	Civil Action No. 01-12257-PBS
)	
)	Judge Patti B. Saris
)	
THIS DOCUMENT RELATES TO )	[FILED UNDER SEAL
01-CV-12257-PBS AND 01-CV-339 )	PURSUANT TO COURT ORDER]
)	

**DECLARATION OF ERIC M. GAIER, PH.D., IN SUPPORT OF  
TRACK 1 DEFENDANTS' JOINT MOTION FOR SUMMARY JUDGMENT**

**March 15, 2006**

Declaration of Eric M. Gaier, Ph.D.

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Declaration of Eric M. Gaier, Ph.D.

## **I. Summary of qualifications**

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- (1) I am a Partner and founding Member of Bates White, LLC (“Bates White”), a professional services firm that performs economic and statistical analysis in a variety of industries and forums. Since I have previously described my qualifications to this Court, I will not repeat them here.<sup>1</sup>

## **II. Scope of charge**

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- (2) I have been retained by counsel for the defendant manufacturers to conduct an analysis of physician-administered drug purchases made by third-party payors (“TPPs”) in Massachusetts.

## **III. Materials considered**

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- (3) I have previously submitted two declarations in relation to this case. On October 25, 2004, I submitted a declaration supporting defendants’ opposition to class certification, and on January 21, 2005, I submitted a sur-reply to the analysis of plaintiffs’ expert Dr. Raymond S. Hartman.<sup>2</sup> Since that time, I have reviewed the December 15, 2005 declarations of plaintiffs’ experts Drs. Raymond S. Hartman and Meredith Rosenthal as well Dr. Hartman’s February 3, 2006 addendum to his declaration. I have also reviewed additional materials, both publicly available and provided through discovery. A summary of the additional materials I have reviewed since my previous declaration is provided in Appendix A.

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<sup>1</sup> *Declaration of Eric M. Gaier, Ph.D. in Support of Defendants’ Opposition to Class Certification*, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS, October 25, 2004, (“Gaier Declaration”), p. 4. Also see Gaier Declaration, Appendix A.

<sup>2</sup> I include these previous declarations by reference here.

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## **IV. Drug purchases made by TPPs**

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- (4) As I discussed in my previous declarations, knowledge regarding the differences between AWP and provider acquisition costs, as a matter of economic theory, would prevent payors from overpaying for prescription drugs as a result of the alleged AWP scheme and therefore insulate them from economic harm.<sup>3</sup> As plaintiffs' expert Dr. Hartman states:

Had the existence of the 'mega-spreads' been perceived and understood by TPPs, those payors would have negotiated more aggressively than they did, leading to lower reimbursement rates.<sup>4</sup>

Judge Saris also recognizes the importance of knowledge and sophistication of TPPs. Specifically, she states:

Some TPPs may have greater sophistication because they purchase self-administered drugs, but there is no evidence that TPPs purchase physician-administered drugs or know of the mega-spreads that exist for these drugs.<sup>5</sup>

It is therefore appropriate to focus on the question of what TPPs in Massachusetts knew about the differences between AWP and provider acquisition costs, and in particular on whether they would have gained knowledge through purchases of physician-administered drugs. The evidence demonstrates that TPPs covering approximately 70 percent of beneficiaries in Massachusetts bought physician-administered drugs throughout the class period. Through those purchases Massachusetts TPPs knew of the widely varying differences between AWP and provider acquisition costs, generally knew the magnitude of these differences, and were aware of those differences since at least 1991 (the earliest date covered by data provided by defendants).

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<sup>3</sup> Gaier Declaration, Section IV.4. Also see *Sur-Reply Declaration of Eric M. Gaier, Ph.D. in Support of Defendants' Opposition to Class Certification*, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS, October 25, 2004, ("Gaier Sur-Reply Declaration"), Section V.

<sup>4</sup> Hartman Liability and Damages Declaration, p. 10.

<sup>5</sup> *Memorandum and Order Re: Motion for Class Certification*, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257, August 16, 2005, ("Saris' Class Certification Order"), p.59.

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- (5) The provision of health insurance in Massachusetts is relatively concentrated, with approximately 86 percent of the covered lives insured by five TPPs. Indeed, named plaintiff and class representative Blue Cross and Blue Shield of Massachusetts (“BCBS-MA”) is the largest TPP in Massachusetts, insuring approximately 46 percent of the covered lives in 2004. BCBS-MA also offers Medicare Supplemental Insurance (“Medigap”) plans to beneficiaries in Massachusetts.<sup>6</sup> It is instructive to also examine other large plans in Massachusetts; Table 1 summarizes the covered lives for the largest TPPs in Massachusetts.

**Table 1: Massachusetts health plans by number of enrollees**

Health plan	Total enrollees (1,000s)	Share of covered lives
Blue Cross Blue Shield of Massachusetts	2,288	46%
Tufts Associated Health Plan (“Tufts”)	803	16%
Harvard Pilgrim Health Care, Inc. (“Harvard Pilgrim”)	766	15%
CIGNA HealthCare of Massachusetts, Inc. (“CIGNA”)	229	5%
Fallon Community Health Plan (“Fallon”)	187	4%
Other (10 plans with more than 1,000 enrolled)	695	14%
<b>Total</b>	<b>4,969</b>	<b>100%</b>

Sources: AIS database, 2004.

- (6) Sales data provided by defendants demonstrate that four of the top five Massachusetts TPPs—plaintiff BCBS-MA, Harvard Pilgrim, CIGNA, and Fallon—purchased physician-administered drugs directly through contracts with manufacturers, through group purchasing organizations (“GPO”s), or through drug wholesalers. These purchases were made by organizations that provided medical care, required a supply of drugs for their operation, and were owned by these TPPs.<sup>7</sup> For example, Harvard Pilgrim and Fallon were staff/group-model HMOs, which are vertically integrated entities that provide both health care and insurance services. Although this form of integrated health plan arrangement is less prevalent

<sup>6</sup> [http://www.mass.gov/doi/Consumer/HealthLists/medicare\\_2006.PDF](http://www.mass.gov/doi/Consumer/HealthLists/medicare_2006.PDF)

<sup>7</sup> See Appendix C for documentation of entities operated by these Massachusetts TPPs for which manufacturers document sales of physician-administered drugs.

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today, many insurers owned, or operated such entities during the 1990s and would have purchased physician-administered drugs.<sup>8</sup>

- (7) The available evidence from manufacturers shows that these TPPs purchased significant volumes of physician-administered drugs, including many of the drugs in this litigation. Table 2 lists dollar volumes of subject physician-administered drugs purchased by these payors, by manufacturer. In addition, those TPP drug purchases were made over an extended period—spanning the entire class period—and starting at least as early as 1991 (the earliest time period for which data have been provided by defendants). Table 3 lists dollar volumes of subject physician-administered drugs purchased by these TPPs over time.

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<sup>8</sup> See Kongstvedt, Peter R. *The Managed Care Handbook*, Aspen Publishers, Gaithersburg, 2001, pp. 34-36 for a description of this type of organization.



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**Table 2: Dollar volumes of subject drugs purchased directly by Massachusetts TPPs, by manufacturer**

Manufacturer	Time coverage of available data	BCBS-MA <sup>9</sup>	CIGNA <sup>10</sup>	Fallon <sup>11</sup>	Harvard Pilgrim <sup>12</sup>
AstraZeneca	91–04		\$1,725,836	\$1,275,699	\$1,231,925
Bristol-Myers Squibb	93–02	\$138,389	\$1,099,332	\$942,688	\$706,249
GlaxoSmithKline	97–01	\$195,951	\$3,933,904	\$875,213	\$1,371,627
Johnson & Johnson	91–99	\$511,377	\$3,595,116	\$1,077,477	\$1,172,335
Schering-Plough	91–04	\$96,549	\$5,178,432	\$2,591,897	\$2,048,990
<b>Total</b>		<b>\$942,265</b>	<b>\$15,532,620</b>	<b>\$6,762,975</b>	<b>\$6,531,127</b>

Source: AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, and Schering-Plough indirect sales data.

<sup>9</sup> I include all purchases in which plaintiff BCBS-MA or its related entities are listed as customers or contract owners in manufacturer chargeback data. Plaintiff BCBS-MA-related entities purchasing subject drugs directly from manufacturers include HMO Blue, Medical East, and Medical West.

<sup>10</sup> I include all purchases in which CIGNA or its related entities are listed as customers or contract owners in manufacturer chargeback data. CIGNA-related entities purchasing subject drugs directly from the manufacturers include CIGNA Healthplan, CIGNA Pharmacy, Connecticut General Life Insurance Company, INA Healthplan, Lovelace, Tel-Drug, EQUICOR, and Healthsource.

<sup>11</sup> I include all purchases in which Fallon or its related entities are listed as customers or contract owners in manufacturer chargeback data. Fallon-related entities purchasing subject drugs directly from manufacturers include Fallon Community Health Care, Fallon Clinic, and Fallon Central Pharmacy.

<sup>12</sup> I include all purchases in which Harvard Pilgrim or its related entities are listed as customers or contract owners in manufacturer chargeback data. Harvard Pilgrim-related entities purchasing subject drugs directly from manufacturers include Harvard Pilgrim Healthcare, Harvard Community Health Plan, Harvard Vanguard, and Rhode Island Group Health (also known as Harvard Community Health Plan of New England).

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**Table 3: Dollar volumes of subject drugs purchased directly by Massachusetts TPPs, by year**

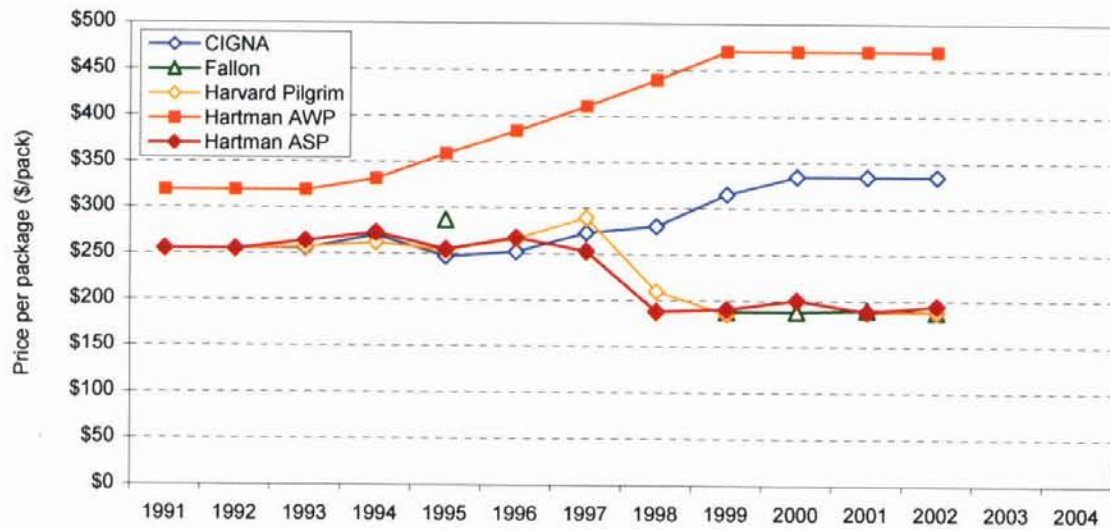
Year	BCBS-MA	CIGNA	Fallon	Harvard Pilgrim
1991	\$873	\$333,323	\$36,258	\$79,334
1992	\$24,757	\$676,409	\$60,983	\$153,853
1993	\$56,739	\$969,456	\$182,672	\$224,164
1994	\$97,608	\$1,252,642	\$296,381	\$349,408
1995	\$123,943	\$1,525,829	\$187,848	\$514,739
1996	\$204,843	\$1,549,650	\$426,002	\$908,120
1997	\$275,633	\$1,739,627	\$785,632	\$1,331,506
1998	\$104,916	\$2,218,061	\$1,100,364	\$1,142,811
1999	\$27,136	\$1,850,194	\$1,185,501	\$870,944
2000	\$20,829	\$1,444,482	\$949,111	\$371,965
2001	\$4,989	\$1,191,893	\$959,915	\$379,568
2002		\$583,350	\$539,284	\$142,822
2003		\$154,352	\$45,639	\$47,424
2004		\$43,352	\$7,385	\$14,469
<b>Total</b>	<b>\$942,265</b>	<b>\$15,532,620</b>	<b>\$6,762,975</b>	<b>\$6,531,127</b>

Source: AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Johnson &amp; Johnson, and Schering-Plough indirect sales data.

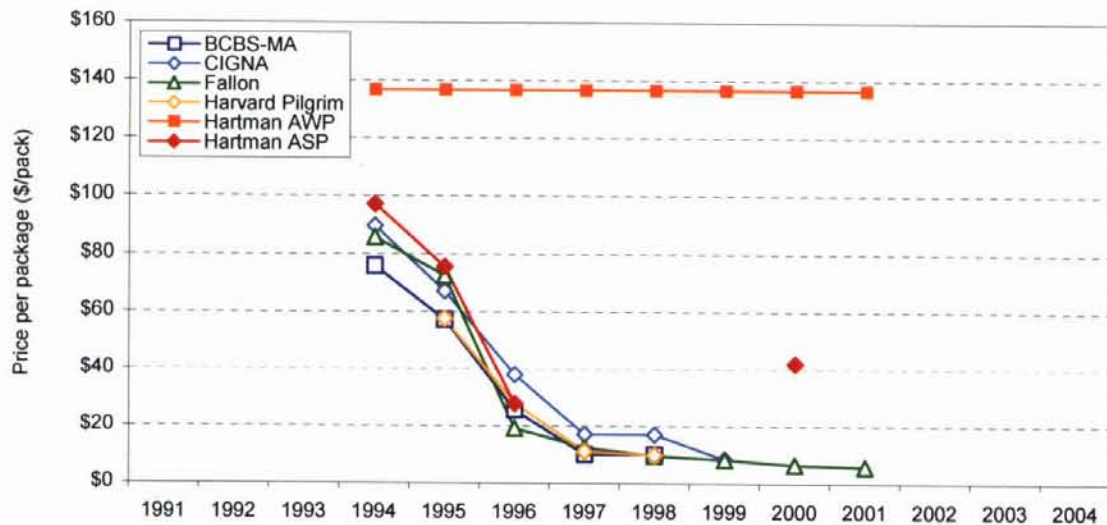
- (8) Importantly, these Massachusetts TPPs purchased physician-administered drugs at discounted prices generally at, and in many cases below, the ASPs calculated by plaintiffs' expert Dr. Hartman. Therefore, these TPPs would have known about the widely varying differences between AWP and provider acquisition costs and would have known about the magnitude of these differences for the very drugs for which Dr. Hartman purports to find damages. Figure 1 to Figure 5 below depict the AWP and ASP reported by Dr. Hartman along with the average discounted prices paid by the Massachusetts TPPs for a sample of the physician-administered drugs for which Dr. Hartman finds damages. Appendix B contains corresponding figures for additional subject drugs purchased by Massachusetts TPPs.



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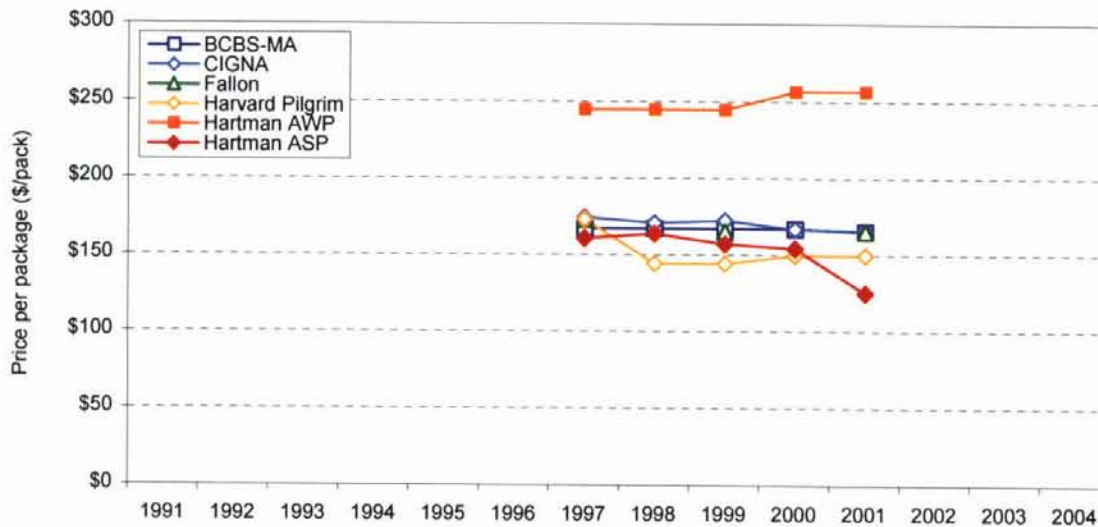
**Figure 1: Zoladex prices to Massachusetts TPPs**

Source: AstraZeneca indirect sales table—NDC 00310096036

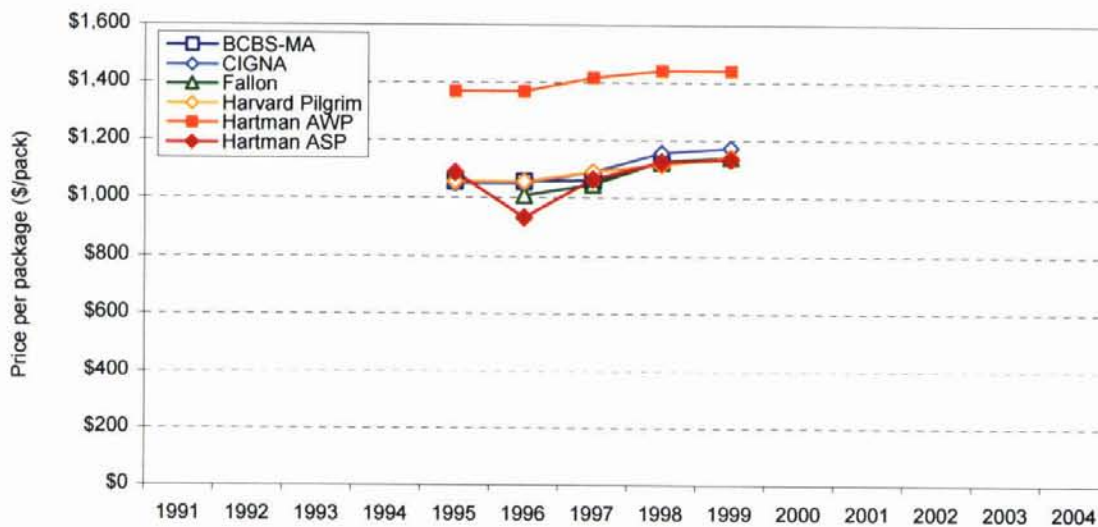
**Figure 2: Vepesid prices to Massachusetts TPPs**

Source: Bristol-Myers Squibb indirect sales data—NDC 00015309520

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**Figure 3: Zofran prices to Massachusetts TPPs**

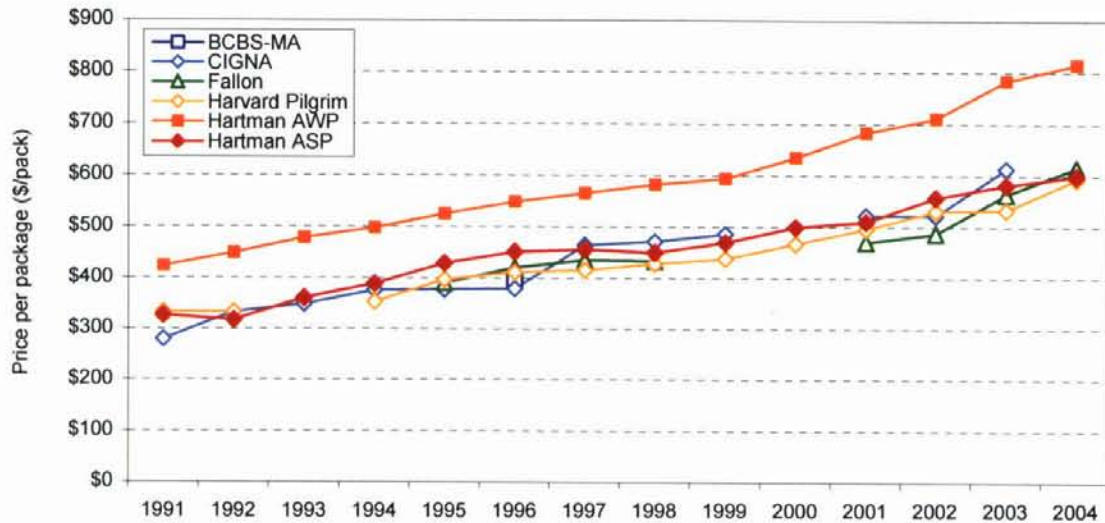
Source: GlaxoSmithKline indirect sales tables—NDC 00173044200

**Figure 4: Procrit prices to Massachusetts TPPs**

Source: Johnson &amp; Johnson indirect sales table—NDC 59676031201

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**Figure 5: Intron prices to Massachusetts TPPs**



Source: Schering-Plough indirect sales tables—NDC 00085053901

- (9) The manufacturers' sales data demonstrate that at least four of the largest five TPPs in Massachusetts—including plaintiff BCBS-MA and collectively representing approximately 70 percent of the beneficiaries in Massachusetts—had knowledge that the subject physician-administered drugs were available to providers at substantial discounts from AWP and knew the magnitude of those discounts since at least 1991. This is the very information that Dr. Hartman concedes would have caused payors to have “negotiated more aggressively than they did, leading to lower reimbursement rates.”<sup>13</sup>

<sup>13</sup> Hartman Liability and Damages Declaration, p. 10.

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I declare under penalty of perjury that this declaration is true and correct.

A handwritten signature in black ink, appearing to be 'E. Gaier', written over a horizontal line.

Eric M. Gaier, Ph.D.

March 15, 2006

Date

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## **Appendix A: Materials considered**

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### **Declarations**

- *Declaration of Eric M. Gaier, Ph.D. in Support of Defendants' Opposition to Class Certification*, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS, October 25, 2004
- *Declaration of Raymond S. Hartman In Support of Plaintiffs' Claims of Liability and Calculation of Damages*, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS, December 15, 2005
- *Liability Report of Dr. Meredith Rosenthal*, December 15, 2005.
- *Memorandum and Order Re: Motion for Class Certification*, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257, August 16, 2005
- *Sur-Reply Declaration of Eric M. Gaier, Ph.D. in Support of Defendants' Opposition to Class Certification*, U. S. District Court for the District of Massachusetts, MDL No. 1456, Civil Action: 01-CV-12257-PBS, October 25, 2004

### **Depositions**

- Mulrey, Michael: Blue Cross Blue Shield of Massachusetts

### **Electronic data**

- AstraZeneca Chargeback Data
  - cntmgt\_pulmicortresp\_indirect\_sales
  - cntmgt\_zoladex\_indirect\_sales
  - AZ\_Sales\_Based\_Customers.csv
- Bristol-Myers Squibb Chargeback Data



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- bms\_indirect\_pre1997
- GlaxoSmithKline Chargeback Data
  - cn\_sales\_v
  - tcbline
- Johnson & Johnson Chargeback Data
  - jj\_imhc\_combined\_chargeback
- Schering-Plough Chargeback Data
  - schering\_chargeback\_1991\_1994
  - schering\_chargeback\_1995\_1998
  - schering\_chargeback\_1999\_2001
  - schering\_chargeback\_2002\_2004

### **Publicly available documents**

- AIS's Directory of Health Plans: 2004, MCOs table
- Kongstvedt, Peter R. *The Managed Care Handbook*, Aspen Publishers, Gaithersburg, 2001

### **Websites**

- [http://www.bluecrossma.com/common/en\\_US/aboutUsIndex.jsp](http://www.bluecrossma.com/common/en_US/aboutUsIndex.jsp)
- [http://www.bluecrossma.com/common/en\\_US/healthPlansIndex.jsp?levelOneDotFiveCategory=HMO&levelTwoCategory=HMO+Blue&targetTemplate=titleBodyAddLvl.jsp](http://www.bluecrossma.com/common/en_US/healthPlansIndex.jsp?levelOneDotFiveCategory=HMO&levelTwoCategory=HMO+Blue&targetTemplate=titleBodyAddLvl.jsp)
- [http://www.bluecrossma.com/common/en\\_US/aboutUsIndex.jsp?repId=Repositories.PressReleases.2001PressReleases.pressRelease04052001.xml&levelTwoCategory=News+%28with+Archives%29&isLevelThreeSelected=true&targetTemplate=pressReleaseDetail.jsp&iphl=medical:medical:east](http://www.bluecrossma.com/common/en_US/aboutUsIndex.jsp?repId=Repositories.PressReleases.2001PressReleases.pressRelease04052001.xml&levelTwoCategory=News+%28with+Archives%29&isLevelThreeSelected=true&targetTemplate=pressReleaseDetail.jsp&iphl=medical:medical:east)

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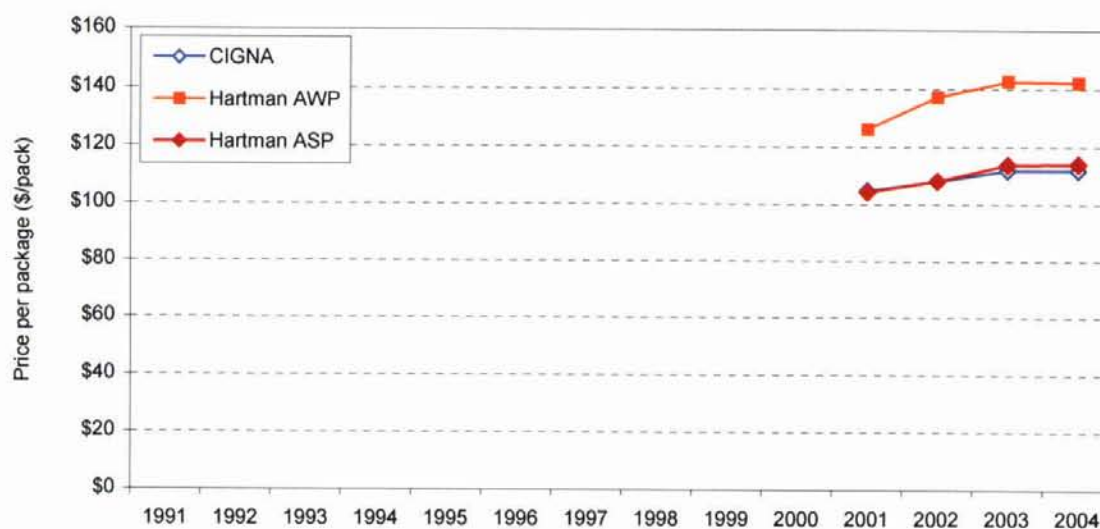
- <http://caselaw.lp.findlaw.com/cgi-bin/getcase.pl?court=1st&navby=case&no=012586>
- [http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list\\_uids=10133054&query\\_hl=2&itool=pubmed\\_docsum](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=10133054&query_hl=2&itool=pubmed_docsum)
- [http://www.cigna.com/health/consumer/service/pharmacy\\_claim.html](http://www.cigna.com/health/consumer/service/pharmacy_claim.html)
- <http://www.cigna.com/general/about/history.html>
- <http://www.cigna.com/general/about/investor/release/10k20021231.html>
- <http://www.ardenthealth.com/CustomPage.asp?PageName=Lovelace>
- <http://www.lovelacesandia.com/CustomPage.asp?guidCustomContentID=A89B6170-7BC2-4F3D-97A5-41F9BA70E1D5>
- [http://www.equityleague.org/PDF/cigna\\_pharmacy\\_guide.pdf](http://www.equityleague.org/PDF/cigna_pharmacy_guide.pdf)
- <http://www.fchp.org/about/index.aspx>
- <http://www.fchp.org/brokers/qa.aspx#Anchor246>
- <http://www.bizjournals.com/boston/stories/2005/01/03/daily50.html>
- <http://www.fallonclinicfoundation.org/ourstory/ourstory.aspx>
- <http://www.fchp.org/SeniorPortal/Sales.aspx>
- <http://www.fallonclinic.com/internet/patients/index.aspx?PAGE=locations&LEVEL1=patients&LEVEL2=locations>
- <http://www.fchp.org/brokers/resources/brokerEdge/BrokerEdgeFall02.pdf>
- <http://www.prospect.org/columns/kuttner/bk000109.html>
- <http://www.bizjournals.com/boston/stories/1999/12/20/story6.html>
- <http://www.harvardvanguard.org/about/faq.asp>
- <http://www.managedcaremag.com/archives/0002/0002.harvard.html>
- [http://findarticles.com/p/articles/mi\\_qa4100/is\\_200506/ai\\_n14715983](http://findarticles.com/p/articles/mi_qa4100/is_200506/ai_n14715983)

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## Appendix B: Additional examples of drugs purchased by Massachusetts TPPs<sup>14</sup>

### AstraZeneca<sup>15</sup>

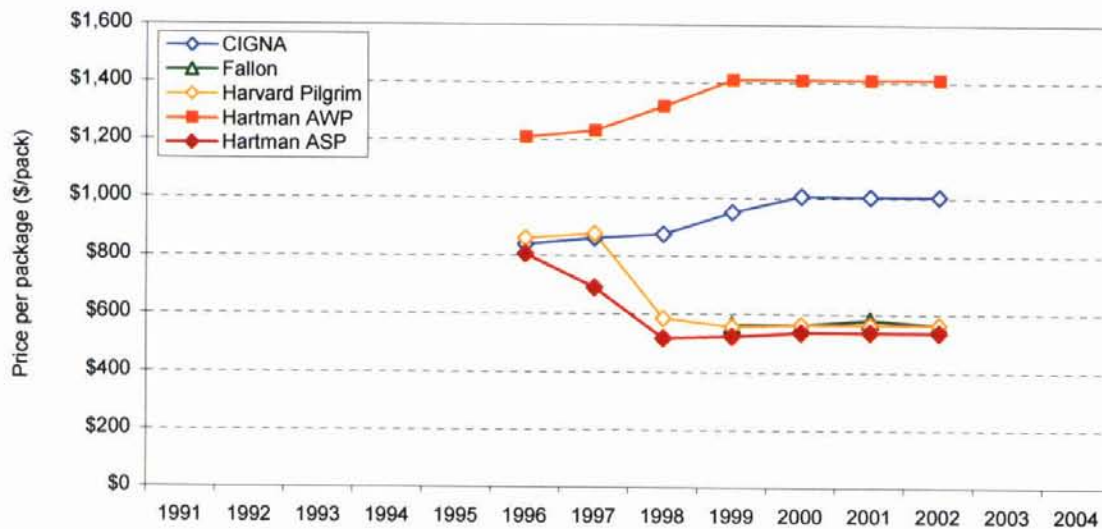
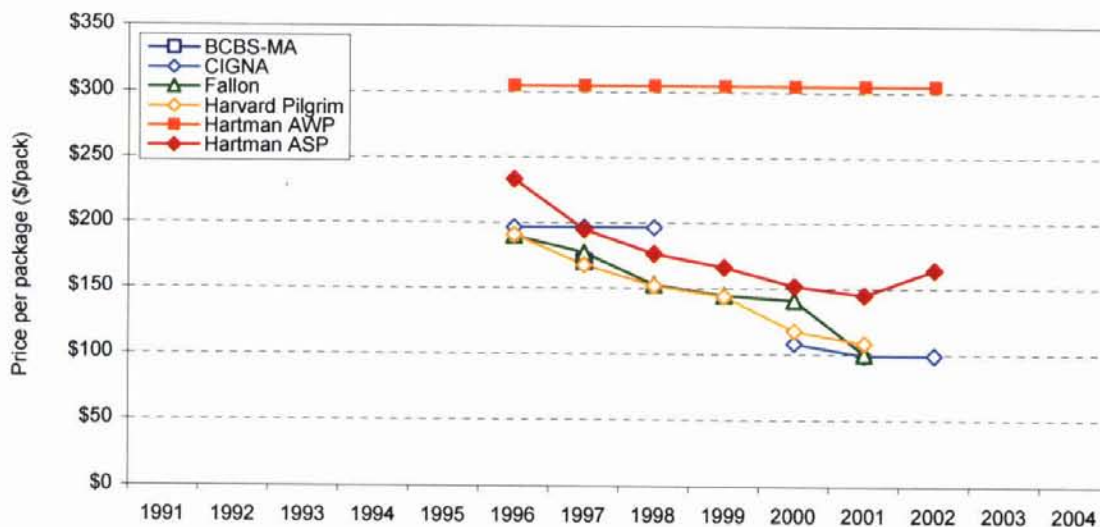
Figure 6: PULMICORT (NDC 00186198804)



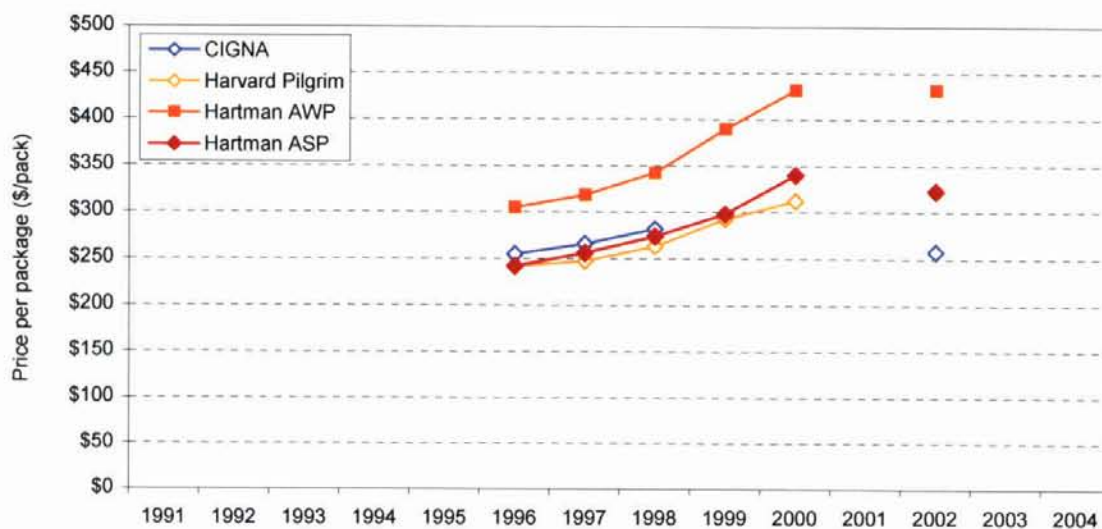
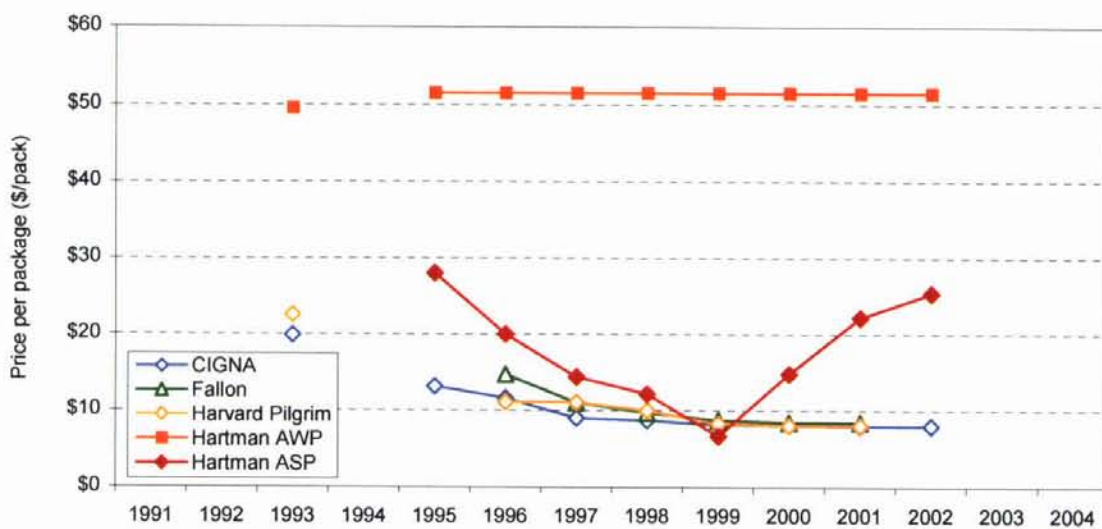
<sup>14</sup> See Appendix C for explanation of the calculation of dollars and prices to Massachusetts TPPs.

<sup>15</sup> Source: AstraZeneca indirect sales table.

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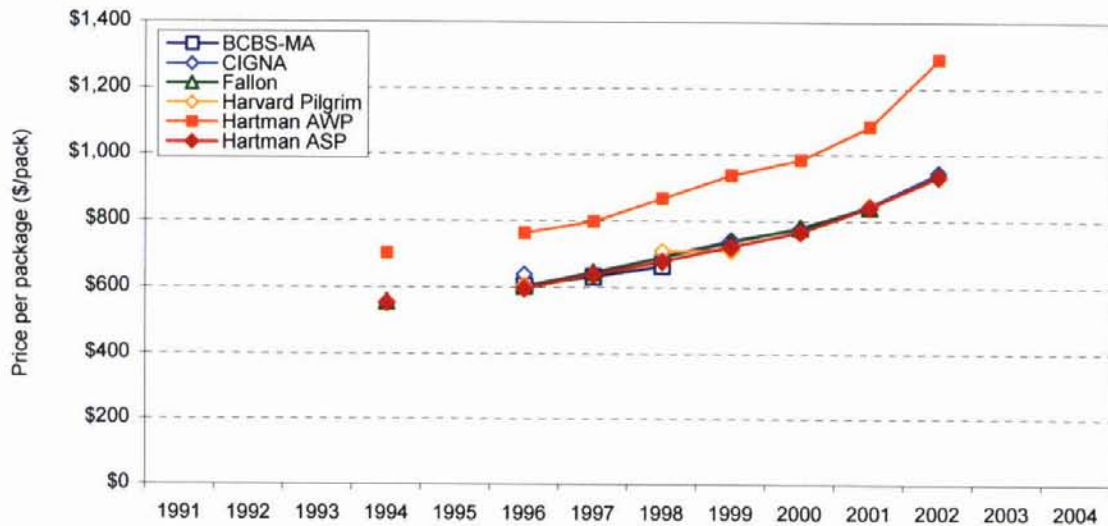
**Figure 7: ZOLADEX (NDC 00310096130)****Bristol-Myers Squibb<sup>16</sup>****Figure 8: BLENOXANE (NDC 00015301020)**<sup>16</sup> Source: Bristol-Myers Squibb indirect sales data.

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**Figure 9: CYTOXAN (NDC 00015050301)****Figure 10: CYTOXAN (NDC 00015054841)**



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**Figure 11: PARAPLATIN (NDC 00015321530)****Figure 12: VEPESID (NDC 00015309145)**